

REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining be allowed.

Claim Amendments

Claim 34 has been canceled without prejudice or disclaimer.

Claims 33 and 36 have been amended to recite multiple sclerosis and rheumatoid arthritis, for which support can be found, for example, at page 2, lines 15-20.

Claim 33 has also been amended to recite that the glycosylated deuterorapamycin is glycosylated at position 42. Support for this amendment can be found, for example, in Figure 5 and canceled claim 34.

Claim 33 has further been amended to recite that the deuterorapamycin is selected from the group consisting of 7-deuteromethyl rapamycin, epi-7-deuteromethyl rapamycin, 31d-rapamycin, 7,43-d₆-rapamycin, 31,42-d₂-rapamycin, and isomers thereof. Support for this recitation can be found, for example, in Figures 1-5 and in the original claim 4.

Claims 33 and 37 have also been amended to remove "solid tumors".

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments. Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

Rejections Under 35 U.S.C. §112, Second Paragraph

The rejection of claims 33-47 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, is obviated-in-part and traversed-in-part for the reasons set forth below.

The claims are directed to methods of using glycosylated deuterorapamycin. The Office Action states that it is not clear where the deuterium or glycosylation is. As amended, the claims now recite a specified group of deuterorapamycin. The claims also indicate that the deuterorapamycin is glycosylated at position 42. Therefore, this part of the rejection is now moot.

The Office Action also states that it is not clear which sugar is attached or how it is attached. Applicants submit that this part of the rejection is improper. Pursuant to MPEP 2171, the second paragraph of 35 U.S.C. §112 sets forth two requirements:

- (A) the claims must set forth the subject matter that applicants regard as their invention; and
- (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

In the instant case, a skilled artisan would understand that the claimed invention relates to a deuterorapamycin that is selected from the specified group and glycosylated at position 42. The word "glycosylated" in the claims would clearly indicate to a skilled artisan that the compound may contain any sugar, attached in any way to position 42. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims,

then the claims comply with 35 U.S.C. 112, second paragraph. Here, since the scope of the claims is clear, and Applicants did not indicate otherwise, the claims are not indefinite.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §112, First Paragraph

A. The rejection of claims 33-47 under 35 U.S.C. §112, first paragraph, as allegedly not being enabled, has been obviated for the reasons set forth below.

The Office Action states that there is no guidance in the specification as to how to make any and all deuterated rapamycins. As amended, the claims recite a deuterorapamycin selected from the group consisting of 7-deuteromethyl rapamycin, epi-7-deuteromethyl rapamycin, 31d-rapamycin, 7,43-d₆-rapamycin, 31,42-d₂-rapamycin, and isomers thereof. Since the specification provides ample guidance to enable a skilled artisan to prepare these compounds (see, e.g., Examples 1-3 (pages 17-20) and Figure 5) teaches the method of glycosylation, the claimed invention is enabled.

B. The rejection of claims 33-37 and 39-47 under 35 U.S.C. §112, first paragraph, as allegedly not being enabled for the treatment of solid tumors or autoimmune diseases generally, has been rendered moot by claim amendments. As amended, the claims no longer recite "solid tumors". Furthermore, the phrase "autoimmune diseases" has been replaced with "multiple sclerosis" and "rheumatoid arthritis". Therefore, this rejection is now moot.

Therefore, withdrawal of these rejections is respectfully requested.

Double Patenting

A. Claims 33-47 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,710,053.

Applicants submit that an appropriate terminal disclaimer will be submitted in due course to overcome this rejection.

B. Claim 38 is rejected under 35 U.S.C. §101 as claiming the same invention as that of claim 5 of U.S. Patent No. 6,710,053 ("the '053 patent"). This rejection has been obviated by the amendment of the claims in the present application. Claim 38, due to the amendment of its base claim 33, now recites a glycosylated deuterorapamycin. Claim 5 of the '053 patent, on the other hand, is not limited to the use of a glycosylated deuterorapamycin. Therefore, these two claims have different scope, and thus they are not directed to the same invention.

In view of the above, withdrawal of this rejection is respectfully requested.

Conclusion

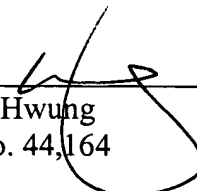
For the reasons set forth above, Applicants submit that subject to the filing of an appropriate terminal disclaimer, the claims of this application are patentable.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.

Enclosed is a \$225.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: Feb. 7, 2005



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